

**REMARKS****1. Status of Application**

The parent application, Ser. No. 10/603,129, includes claims 23-44 and was filed June 24, 2004. No claims have been amended in this response.

**2. Claim Rejections – 35 U.S.C. § 102****a. Cumer**

The Examiner rejected claim 23 under § 35 U.S.C. § 102(b) as being anticipated by Cumer et al. (U.S. 5,665,069) (“Cumer”). The Examiner stated that “Cumer teaches rotational molding (col. 4, line 33) to make silicone syringes (col. 4, lines 38 and 35, respectively). The syringes have inner cavities (Figure 7).” Applicant respectfully submits that rejection based on Cumer is applicable to the claim 23.

The Applicant respectfully submits that Cumer does not teach rotational molding to make silicone syringes with inner cavities. Rather, Cumer teaches the making of a pressure directed flange that attaches to a standard hypodermic needle’s (syringe) hub. (col. 1, line 67 to col. 2, line 1). The Examiner has misinterpreted the passage related to the molding of the flange to incorporate the syringe. Cumer teaches a flange that has a portion defining a tunnel, to receive a hub of a hypodermic needle so that a hub is held substantially perpendicular to the flange and the hub extends sufficiently outwardly from said second side of the flange so that it is able to receive the connection of a standard syringe barrel. (col. 2, line 3 to line 10). The Examiner has misinterpreted the passage (col. 4, line 26 to line 40) related to the molding of the flange to include the syringe when, in fact, the Cumer invention is related to only the flange which does not disclose a cavity. Cumer does not teach or disclose a multi-axis rotationally medical article

that includes an interior cavity. Applicant respectfully submits that claims 23 is patentable over the prior art of record.

**b. Shah**

The Examiner rejected claims 23, 35 and 42 under § 35 U.S.C. § 102(e) as being anticipated by Shah (U.S. 6,291,543, filed on May 24, 2000). The Examiner stated that Shah teaches catheters made by rotomolding compositions containing silicones or polyurethanes. Applicant submits a 37 C.F.R. 1.131 Affidavit (“1.131 Affidavit”) by the sole inventor, David Schuessler, to overcome the Shah patent by proving the invention of the claimed subject matter by Applicant was prior to the effective date of Shah reference upon which the Examiner basis this rejection. See Exhibit A of 1.131 Affidavit. The effective date of the Shah application is May 24, 2000. As attested in the 1.131 Affidavit, Applicant has conceived of the subject matter of the invention at least as early as February 18, 1999. Applicant respectfully submits that claims 23, 35 and 42 are patentable over the prior art of record.

**c. O’Hara**

The Examiner rejected claims 23, 35 and 42 under § 35 U.S.C. § 102(e) as being anticipated by O’Hara (U.S. 6,231,547, filed on February 18, 1999). Examiner states that O’Hara shows catheters made by rotomolding polyurethanes or silicones. Applicant submits the 1.131 Affidavit of the sole inventor, David Schuessler, to overcome O’Hara by proving the invention of the claimed subject matter by Applicant was prior to the effective date of O’Hara reference upon which the Examiner basis this rejection. See Exhibit A of 1.131 Affidavit. The effective date of the O’Hara application is February 18, 1999. As attested in the 1.131 declaration, Applicant has conceived of the subject matter of the invention at least as early as

February 18, 1999. Applicant respectfully submits that claims 23, 35 and 42 are patentable over the prior art of record.

### **3. Claim Rejections – 35 U.S.C. § 103**

#### **a. Claims 23 and 40**

Claims 23 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Hara in view of Yoshino (U.S. Patent No. 5,519,082). As discussed above, Applicant has been able to successfully demonstrate that Applicant conceived of the subject matter of the invention prior to the effective date of the O'Hara patent. Applicant respectfully submits that claims 23 and 40 are patentable over the prior art of record.

#### **b. Claims 23, 35, and 41**

Claims 23, 35 and 41 are rejected under 35 U.S.C. § 103(a) as being unpatentable over O'Hara in view of Revis (U.S. 5,091,445). ). As discussed above, Applicant has been able to successfully demonstrate show that Applicant conceived of the subject matter of the invention prior to the effective date of the O'Hara patent. Applicant respectfully submits that claims 23, 35 and 41 are patentable over the prior art of record.

### **4. Nonstatutory Double Patenting Rejection**

The Examiner rejected claims 39-44 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 23-38 of copending Application No. 10/603904.

On June 24, 2004, Applicant filed a copending Application No. 10/603904 ("the '904 application"), with claims 1-38. Also on June 24, 2004, Applicant filed a Preliminary Amendment in the '904 application, canceling claims 6-20 and 23-38 to pursue patentability of

claims 1-5 and 21-22. As such, the claims from the '904 application relied on by the Examiner for the obviousness-type double patenting rejection are now canceled and are the same claims present in the above-titled application. Applicant respectfully requests the rejection based on obviousness-type double patenting be withdrawn.

#### **5. Statutory Double Patenting Rejection**

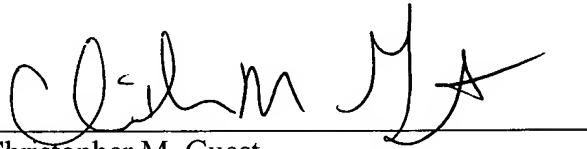
The Examiner rejected claims 23-38 as provisionally rejected under 35 U.S.C. § 101 as claiming the same invention as that of claims 23-38 of the '904 application.

On June 24, 2004, Applicant filed the copending the '904 application, with claims 1-38. Also on June 24, 2004, Applicant filed a Preliminary Amendment in the '904 application, canceling claims 6-20 and 23-38 to pursue patentability of claims 1-5 and 21-22. As such, the conflicting claims of the '904 application relied on by the Examiner for the statutory double patenting rejection are now canceled. Applicant respectfully requests the rejection based on statutory double patenting be withdrawn.

**6. Conclusion**

It is respectfully submitted that the present application as amended is in condition for allowance and prompt notification thereof is requested. If the prosecution of this application can be advanced by a telephone conference, the Examiner is requested to call the undersigned at (212) 530-5363.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Christopher M. Guest", written over a horizontal line.

Dated: March 30, 2005

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